REMARKS

1. Status of Claims.

Claims 1-16, 19, 28-30, and 38 are canceled.

In general, the claims are amended to use consistent terms for the various elements of the invention. No new matter is introduced by these changes in terms.

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Claim 17 is amended to depend from new claim 42. The claim is amended to recite an "implantable **brachytherapy** source". The claim also recites "polyetheretherketone (PEEK)". PEEK is an acronym for polyetheretherketone. Subject matter regarding the capsule that is now recited in claim 42 is deleted from claim 17. Support for the amendments is found in the specification at page 1, lines 4-5; page 2, lines 31-32; and page 14, lines 1-3.

Claim 18 is amended to depend from new claim 42. The claim is also amended to correct the antecedent basis for terms in the claim.

Claim 20 is amended to depend from new claim 42. The claim is amended as a kit claim to more clearly express that a multiplicity of functional units and biocompatible capsules are adapted to form linear strands or planar arrays. The claim is also amended to correct the antecedent basis of the terms within the claim. Support for the amendment is found within the specification at page 3, lines 14-20; page 8, lines 12-30; page 9, lines 8-11; Figures 7A-7D; Figures 8A-8D; Figure 13; and Figure 15.

Claim 21 is amended to depend from new claim 42. The claim is amended to correct the antecedent basis for terms in the claim. Support for the amendments is found within the specification at page 16, 20-25 and original claim 21.

Claim 22 is amended to depend from new claim 42. The claim is also amended to clarify the language in the claim. No new matter is added.

Claim 23 is amended to depend from new claim 42. The claim is also amended to correct the antecedent basis for terms in the claim and clarify the language in the claim. No new matter is added.

Claim 24 is amended to depend from new claim 42. The claim is amended to clarify the language of the claim and correct the antecedent basis for terms in the claim. The recitations concerned with the retaining element and the movement of the seed train through the needle during the implant procedure are deleted from the claim. Support for the amendment is found in the specification in original claim 36 and Figures 13 and 15.

Claim 25 is amended to depend from new claim 42. The claim is also amended to clarify the antecedent basis for terms within the claim.

Claim 26 is amended to depend from new claim 42. The claim is also amended to clarify the antecedent basis for terms within the claim. The subject matter of the method recitation in the claim is deleted from claim 26 and is incorporated in method claim 37.

Claim 27 is amended to depend from new claim 42. The claim is also amended to clarify the language of the claim and the antecedent basis for terms within the claim. Claim 27 is amended to include MRI imaging visible by the method. Support for the amendments is found in the specification at page 3, lines 22-24; page 9, lines 4-5; and page 11, lines 13-17.

Claim 31 is amended to better recite the inventive features of the cylindrical capsule. The claim is also amended to more completely recite the composition of the radioactive seed. The claim is amend to recite that the radioactive seed comprises "epoxy based fluid carrier". Support for the amendments is found in the specification at page 2, lines 13-25 and page 14, lines 20-22.

Claims 32 and 33 are amended to clarify that they are dependent claims and correct the language of the Markush groups. No new matter is added.

Claim 34 is amended to clarify that it is a dependent claim.

Claims 35 and 36 are amended to clarify the language in the claims and clarify the antecedent basis of the terms within the claims. Support for the amendments is found in original claims 35 and 36.

Claim 37 is amended to clarify the antecedent basis of the terms within the claim. The claim is also amended to delete the previously recited step (d) concerning the mold. The claim adds the recitation of suitable sources of therapeutic radiation. The claim is amend to recite that the radioactive seed comprises "epoxy based fluid carrier". The claim also recites physical characteristics of the biocompatible capsule. Support for the amendments is found in the specification at page 3, lines 14-24; page 4, lines 1-6; page 14, lines 20-22; and original claims 4 and 5.

Claim 39 is amended to correct the dependency of the claim and clarify the antecedent basis of terms within the claim. The claim is also amended to clarify the language within the claim and eliminate reference to the mold.

Claims 40 and 41 are amended to clarify the dependency within the claims and to properly recite the Markush groups.

Claim 42 is new and recites more clearly the metes and bounds of the subject matter recited in original claim 16. Claim 42 recites the biocompatible capsule having a "socket at each end". Claim 42 also recites that the radioactive seed comprises an epoxy based fluid carrier. Support for the amendments to the claim is found in the specification at page 8, lines 12-18; page 14, lines 20-22; page 17, lines 5-14; and original claims 10 and 16.

2. Rejection of Claims 1-3, 5, 9-11, 13, 17, 20, 24-26, and 28 under 35 U.S.C. § 112 (2nd Paragraph).

The Examiner asserts that 1-3, 5, 9-11, 13, 17, 20, 24-26, and 28 are indefinite under 35 U.S.C. § 112. Applicant respectfully disagrees.

The rejection is moot with respect to canceled claims 1-3, 5, 9-11, 13, and 28.

Claim 17 is amended to eliminate the phrase "such as" and include within the claim "polyetheretherketone" for which PEEK is an acronym. Claim 20 has been amended as a kit claim. Claim 24 is amended to more clearly express the subject matter and deletes the phrase "if required". Claims 17, 20, 25, 25 and 26 are amended to depend from new claim 42. New claim 42 is presented to provide language which avoids the deficiencies in now-canceled claim 16 (which is similar to canceled claim 1) cited by the Examiner.

Applicant asserts that claims 17, 20, 24, 25, and 26 now distinctly claim the subject matter of the invention. Applicant requests the Examiner to withdraw the rejection.

3. Claim Objections.

The Examiner objected to claims 14 and 15 as being improper multiple dependent claims for failing to refer to other claims in the alternative only.

This objection is moot with respect to claims 14 and 15 because these claims are canceled.

4. Rejections of Claims 1-3, 12, 16-18, and 31-34 under 35 U.S.C. § 102(b).

The Examiner rejected claims 1-3, 12, 16-18, and 31-34 as being anticipated by EP 0996,130 to Ziegler et al ("Ziegler"). Applicant respectfully disagrees.

The rejection is moot with respect to canceled claims 1-3, 12, and 16. However, new claim 42 recites much of the subject matter of original claim 16.

Applicant's independent claim 42 recites a brachytherapy source comprising a biocompatible capsule having "a socket at each end adapted to be affixed to a ball joint of said functional unit to form a linear strand or a planar array." Similarly, claim 31 recites a biocompatible device comprising a hollow outside cylindrical capsule "having a socket at each end adapted to be affixed to a ball joint of said functional unit to form a linear strand or a planar array." Applicant asserts that the socket configuration of the capsules is a novel feature not disclosed by Ziegler.

In addition to providing a connection to a functional unit, the socket helps prevent migration of the capsules when placed in the body. The socket configuration on the seed capsule acts as an anchor when placed in body tissue.

Applicant submits the declarations of Mr. Heiko Jacobs and Dr. Axel Hentrich as support. Both Mr. Jacobs and Dr. Hentrich present evidence that migration of brachytherapy seeds is a problem that is not completely solved by incorporating the seeds into strands.

Applicant's claim 42 recites a radioactive seed comprising "an epoxy based fluid carrier that is resistant to radiation polymerization in its fluid phase, but can be induced to solidify by raising its temperature." Applicant's claim 31 recites "an inside cylindrical solid radioactive seed comprising a marker and a source of therapeutic radiation uniformly mixed with and dispersed throughout an epoxy based fluid carrier." Applicant asserts that Ziegler discloses a radioactive seed comprising a matrix comprising ceramic materials, insoluble minerals, insoluble salts, and inorganic polymers [see paragraph 0019]. Applicant does not recite any of these materials in the claims of the present invention. The porous solid inorganic material disclosed by Ziegler are not suitable for injection via a fluid phase into a biocompatible capsule prior to curing to solidify the material Applicant asserts that Ziegler does not disclose an epoxy based fluid carrier. Furthermore, the epoxy based fluid carrier recited in claim 42 is an organic material rather than an inorganic material as is used for the carriers disclosed by Ziegler.

Applicant also notes that Ziegler adds a marker to the completely formed radioactive seed and does not include the marker as a component along with the sources of therapeutic radiation and the epoxy based fluid carrier as claimed by Applicant..

Applicant notes that Ziegler discloses that the capsule may be formed from phenyetheretherketone [0016] and does not disclose that material as having an acronym of "PEEK". Applicant recites a different substance, polyetheretherketone, as being "PEEK" in claim 17.

Because the subject matter of claims 42 and 31 is not disclosed by Ziegler, Zeigler cannot anticipate these claims. Applicant requests the Examiner to withdraw the rejection and allow the claims 42 and 31. Dependent claims 17-18 and claims 32-34 depend from claims 42 and 31, respectively and include the recitations therein. Thus, these claims should be allowable as well.

5. Rejection of Claims 5, 7, and 20 under 35 U.S.C. § 102(b).

The Examiner rejected claims 5, 7, and 20 as being anticipated by U.S. 6,273,851 to Slater et al ("Slater I"). Applicant respectfully disagrees.

The rejection is moot with respect to canceled claims 5 and 7.

Slater I discloses a radioactive seed having an inner tube coated on both the inner and outer surfaces with a radioactive isotope and a collar surrounding the tube comprising a metal used for a marker. Slater discloses seeds having ball joint ends and connectors having socket-like ends [see column 6, lines 47-54 and Fig. 5]. Applicant asserts that the Slater I configuration is opposite to that of claim 20

which recites a "functional unit having ball joints" and "a socket of said biocompatible capsule". Furthermore, Slater I does not disclose connectors having "1, 2, 3, 4, or 6 ball joints adapted to be affixed to a socket of said biocompatible capsules to form a planar array having triangular, square, and hexagonal patterns" as recited in Applicant's claim 20. Applicant's radioactive seeds also do not comprise a collar as required by Slater I.

Applicant asserts that having the socket end as part of the biocompatible capsule aids in preventing migration of seeds implanted in body tissue. Applicant refers the Examiner to the declarations of Mr. Heiko Jacobs and Dr. Axel Hentrich for support. In addition to providing a connection to a functional unit, the socket help prevent migration of the capsules when placed in the body. The socket configuration on the seed capsule acts as an anchor when placed in body tissue. Both Mr. Jacobs and Dr. Hentrich present evidence that migration of brachytherapy seeds is a problem that is not completely solved by incorporating the seeds into strands.

Claim 20 depends from claim 42 and includes all of the recitations of claim 42 in the recitation of the claim. Applicant asserts that Slater I does not disclose a radioactive seed comprising "an epoxy based fluid carrier" as recited in claim 20.

Because Slater I does not disclose all the features of claim 20, it can not anticipate the claim. Applicant respectfully requests the Examiner to withdraw the rejection and allow the claim.

6. Rejection of Claim 7 under 35 U.S.C. § 102(b).

The Examiner rejected claim 7 as being anticipated by U.S. 5,342,283 to Good.

The rejection is moot with respect to canceled claim 7.

7. Rejection of Claims 8, 9, 23, and 24 under 35 U.S.C. § 102(b).

The Examiner rejected claims 8, 9, 23, and 24 as being anticipated by U.S. 6,264,599 to Slater et al ("Slater II"). Applicant respectfully disagrees.

The rejection is moot with respect to canceled claims 8 and 9.

Slater II discloses a connecting means [160, 260] with a spring [164] or moisture expandable engagement means [266] which are designed to facilitate fixation of the seeds and spacing links within the tissue of the body [column 7, lines 22-34]. Applicant notes that [164] of Slater II represents a spring and not "expandable petals or barbs" as recited in Applicant's claim 23. Applicant asserts that the spring [164] cannot be interpreted as being "a malleable plug comprising a plastic foam which is readily imaged by ultrasound" as recited in Applicant's claim 24.

Claims 23 and 24 depend from claim 42 and includes all of the recitations of claim 42 in the recitation of the claims. Applicant asserts that Slater II does not disclose a radioactive seed comprising "an epoxy based fluid carrier" as recited in claims 23 and 24.

Because Slater II does not disclose all the features of claims 23 and 24, it can not anticipate the claims. Applicant respectfully requests the Examiner to withdraw the rejection and allow claims 23 and 24.

8. Rejection of Claim 27 under 35 U.S.C. § 102(b).

The Examiner rejected claim 27 as being anticipated by U.S. Application 2002/0058853 to Kaplan ("Kaplan"). Applicant respectfully disagrees.

Kaplan discloses a brachytherapy seed comprising a biocompatible component, a therapeutically active component, and a radiopaque marker which can be an element such as palladium, platinum, iridium, gold, etc or a polymer [see paragraphs 0045 and 0047]. However, the marker is used in conjunction with a pre-formed seed [0046], for example as a band or ring placed along the outer surface of the seed. The marker of Kaplan is not a component of the radioactive seed contained within the biocompatible capsule as recited in Applicant's claim 42 from which claim 27 depends.

Claim 27 depends from claim 42 and includes all of the recitations of claim 42 in the recitation of the claim. Applicant asserts that Kaplan does not disclose a radioactive seed comprising "an epoxy based fluid carrier" as recited in claim 27.

Because Kaplan does not disclose all of the elements of claims 27, it can not anticipate the claims. Applicant respectfully requests the Examiner to withdraw the rejection and allow claims 27.

9. Rejection of Claims 4, 19, 35, and 36 under 35 U.S.C. § 103(a).

The Examiner rejected claims 4, 19, 35, and 36 as being obvious in view of Ziegler and Slater I.

The rejection is moot with respect to canceled claims 4 and 19.

The Examiner asserts that it would have been obvious to provide the seed of Ziegler with the connectors taught by Slater I to form a seed strand as taught by Slater I in Figures 5 and 8. Applicant respectfully disagrees.

Applicant reasserts arguments against Ziegler presented above in Section 4 with respect to claim 31 from which claims 35 and 36 depend. Furthermore Ziegler does not disclose "a hollow cylindrical capsule..... having a socket at each end..." as recited by Applicant in claim 31 from which claims 35 and 36 depend.

Applicant's claim 35 recites "functional unit having one or more ball joint elements." Applicant's claim 36 recites a "said biodegradable functional unit is comprised of one ball joint element, two ball joint elements, three ball joint elements, four ball joint elements or six ball joint elements." Figures 5 and 8 of Slater I do not exemplify or suggest connectors (functional units) with ball joint elements. The connectors in Slater I are of the opposite configuration of that recited by Applicant in claim 31 from which claims 35 and 36 depend. One of ordinary skill in the art would not be motivated to reverse the configuration of the ball and socket joints in Slater I.

Furthermore, Applicant submits the declarations of Mr. Heiko Jacobs and Dr. Axel Hentrich to support that the reverse configuration recited in claims 35 and 36 provides the unexpected benefit of preventing seed migration when the seed is implanted in human tissue. Applicant asserts that the preferred configuration is to have ball joint elements as components of the functional units and socket elements as components of the biocompatible capsules.

Claims 35 and 36 depend from claim 31 and includes all of the recitations of claim 31 in the recitation of the claims. Applicant asserts that neither Ziegler nor Slater I disclose or suggest a radioactive seed comprising "an epoxy based fluid carrier" as recited in claims 35 and 36.

Because the combination of Ziegler and Slater I does not disclose or suggest all of the elements of claims 35 and 36, they can not make obvious the claim. Applicant respectfully requests the Examiner to withdraw the rejection and allow claims 35 and 36.

10. Rejection of Claims 6, 7, 21, and 22 under 35 U.S.C. § 103(a).

The Examiner rejected claims 6, 7, 21, and 22 as being obvious in view of Slater I and U.S. 6,159,143 to Lennox ("Lennox").

The rejection is moot with respect to canceled claims 6 and 7.

The Examiner asserts that Slater I discloses a functional unit (spacer) but does not teach an adjunctive therapy to be release by the spacer. Lennox is said to provide the teaching of an adjunctive therapy spacer. Applicant respectfully disagrees.

Applicant asserts that Lennox discloses that the "invention is a device, and the method of use thereof, that replaces the seed spacers currently known in the art..." [see column 3, lines 19-27]. Applicant further asserts that the disclosure of Lennox is an expressed teaching away from the concept of using a connecting spacer or "functional unit" as recited in claims 21 and 22. Thus, there would be no motivation to one of ordinary skill in the art to combine Lennox with Slater I as the Examiner has suggested.

Applicant also notes that the seeds and adjunctive therapeutic of Lennox are

placed within a device, for example a strip, a monofilament, or a mesh patch to produce arrays [see column 4, lines 14-52]. The seeds and adjunctive therapeutics do not have connecting devices attached thereto and are not physically attached to each other in a ball - socket configuration as described in Applicant's invention.

Claims 21 and 22 depend from claim 42 and includes all of the recitations of claim 42 in the recitation of the claims. Applicant asserts that neither Slater I nor Lennox disclose or suggest a radioactive seed comprising "an epoxy based fluid carrier" as recited in claims 21 and 22.

Because the combination of Slater I and Lennox does not disclose or suggest all of the elements of claims 21 and 22, it can not make obvious the claims. Applicant respectfully requests the Examiner to withdraw the rejection and allow claims 21 and 22.

11. Rejection of Claims 13, 28, 29, and 30 under 35 U.S.C. § 103(a).

The Examiner rejected claims 13, 28, 29, and 30 as being obvious in view of Ziegler and U.S. 3,351,049 to Lawrence.

The rejection is moot with respect to canceled claims 13, 28, 29, and 30.

12. Rejection of Claims 37-41 under 35 U.S.C. § 103(a).

The rejection is moot with respect to canceled claim 38.

The Examiner asserts that Ziegler teaches a method as claimed by Applicant but uses a ceramic carrier in Example 2. Ziegler is said to disclose using a polymer in Example 1 or 2. The Examiner concludes that it would have been obvious to one of ordinary skill in the art to use the method set forth in the example to use injection molding with the polymer of Example 2. The combination is said to produce an expected result because both methods are set forth by Ziegler. Applicant respectfully disagrees.

Applicant asserts that Ziegler discloses a method for preparing a radioactive seed comprising a radioactive carrier matrix which consists of a porous and mechanically stable inorganic material, iodide-125, and may contact an X-ray marker [Abstract]. Example 2 discloses the injection molding process wherein the carrier matrix slurry comprised of aluminum oxide, cellulose powder, paraffin, water silver chloride and active exchange solution of NaI-125 is subjected to the hot injection molding process wherein the hot slurry is poured into a mold and cooled to solidify. The formed seeds are removed and heated to cure the resulting silver iodide-125 distributed within the ceramic matrix. After cooling again the marker is inserted and the mold is sealed. Ziegler discloses that the porous inorganic materials of the matrix include inorganic polymers [paragraph 0019] and may be coated with plastic materials [paragraphs 0016 and 0017].

Applicant asserts that Ziegler does not suggest the method of claim 37 which comprises "mixing a source of therapeutic radiation dispersed in an epoxy based fluid carrier...to form a fluid homogenous radioactive mixture; ... injecting said fluid homogenous radioactive mixture through an ink-jet head into said hollow outside cylindrical capsule;...and heating the fluid homogenous radioactive mixture to form said solid radioactive seed."

Applicant's method claim 37 recites "a source of therapeutic radiation dispersed in an epoxy based fluid carrier." Applicant asserts that Ziegler discloses a radioactive seed comprising a matrix comprising ceramic materials, insoluble minerals, insoluble salts, and inorganic polymers [see paragraph 0019]. The porous solid inorganic material disclosed by Ziegler is not suitable for injection via a fluid phase into a biocompatible capsule prior to curing to solidify the material. Applicant asserts that Ziegler does not disclose an epoxy based fluid carrier as recited in claim 37. Furthermore, the epoxy based fluid carrier of claim 37 is an organic material. In contrast, Ziegler teaches a carrier comprised of an inorganic material.

Applicant also notes that Ziegler adds a marker to the completely formed radioactive seed and does not include the marker as a component along with the sources of therapeutic radiation and the epoxy based fluid carrier.

Because the subject matter of claim 37 is not disclosed or suggested by Ziegler, Zeigler cannot make obvious this claim. Applicant requests the Examiner to withdraw the rejection and allow the claim 37. Claims 39-41 depend from claim 37 and includes the recitations therein. Thus, these claims should be allowable as well.

CONCLUSION

This is intended to be a complete response to the outstanding Examiner's Action. If any questions remain, the Examiner is invited to phone Applicant's representatives at the number and/or email addresses given below.

Respectfully submitted: November 4, 2010

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